

SPL ER/DL Team

Aug 1, 2012

Minutes

Chair: Pat Cowall-Hanover

Call in information:

Number: 866-213-21456

Passcode: 2738216

CMS Letter and Questions around Drug Listing Data:

The CMS Letter from May 14, 2012 was discussed at the SPL Process Team meeting on July 25, 2012. Several questions /areas of clarification arose. We discussed these at the meeting and identified several things that we would like to clarify with either Craig Miner from CMS or Lonnie Smith:

- 1. We know that several sponsors were contacted and asked to update their market start dates.**
 - a. If a sponsor hasn't been contacted to review/modify its market start dates, can a sponsor assume that the market start dates are acceptable?
 - b. Sponsors can verify their list, but how will they know it's the same as the one CMS is referencing?
 - i. Where/how did CMS pull the market start date that they are using as a comparison?
 - ii. Where can a sponsor get a list of the market start dates that CMS is using?
 - iii. Does the market start date have to be exact to the date CMS is using as the comparison – or close to the market start date? What is acceptable?
 - c. How does a sponsor correct the dates?
 - i. One sponsor commented that they found discrepancies in the dates between the NSDE and the CMS "non-matched list." [[They used a submission date instead of the approval and/or market start date.]] The incorrect dates have since been corrected in the SPL. However, the market start dates listed in the NSDE file are still the old "incorrect" ones.

2. The NSDE spreadsheet seems to use the following process for determining the market start date:

- For product/packs drug listing prior to June 1, 2009, the market start date is the date included in the SPL market start date for the product.
 - For new pack sizes (for which SPL does not have a market start date), the market start date appears to be the date the SPL file is loaded into FDA's database.
 - For new products drug listed after June 1, 2009, the market start date is not the market start date. It appears to be the date the SPL file was loaded into the FDA database.
- a. Please explain the rules that are being used to calculate/infer the market start dates in the NSDE files. Also please explain the process that we should use for drug listing our products – so that our products can be reimbursed appropriately. Specific questions are provided below.
- i. How are the market start dates and market end dates being derived for use in the NSDE spreadsheet ?
 - 1. New product
 - 2. New pack within an existing product
 - 3. Deletion of a pack within an existing product
 - 4. Deletion of product (ie remaining packs for the product)
 - ii. Can we submit SPL for drug listing with future dates, instead of drug listing at the actual time the product is launched? Examples:
 - 1. Market start date: Sponsors are instructed to elist approvals (including new products) within 14 days – even though the actual launch of the product is in the future. If a product isn't going to be launched for several weeks/months, what do we put as a market start date for these products that won't be marketed for several weeks/months? Leave them blank?
 - 2. Market end date: After a product has been discontinued, the product could remain on pharmacy shelves and be sold until expiration of the last lot. Can sponsors put in a future market end date representing the last lot expiry? What date will be put in the NSDE file – ie when will reimbursement start being denied?
- b. Since our reimbursements may be in jeopardy, we are very concerned about these dates being calculated/inferred.
- i. We understand that the SPL file is not set up to track market start dates on the pack size level. Ie market start and end dates for an individual pack size need to be calculated based on the date the pack is added / removed from a product.
 - ii. Please explain the rationale for using a calculated/inferred date for market start dates for a new product instead of the market start date provided in the SPL drug listing file.

3. In the CMS letter of May 14, 2012, a process was defined for how CMS will manage NDCs when NDCs are listed more than once with different information. Quote from the letter:

CMS understands that sometimes conflicting information may occur on the NSDE file. Below is a chart that outlines how CMS will edit NDCs when NDCs are listed more than once with different information:

- a. Would you please give examples for situations when an NDC code can be listed more than once? We've provided one example below, but there are probably others.
- b. For the assignment of the market end date, the CMS letter states that the earlier market end date would be used (ie the 9/30/2012 date in the last column).

End Date	09/30/2012	11/30/2012	09/30/2012
----------	------------	------------	------------

Based on the scenario described below, we think that product may not be reimbursed appropriately if the earlier market end date is used. Please review the example below to determine if this is an example of duplicate NDCs and whether the NDC would be reimbursed.

Oral product, individual blister packs (NDC code 1234-5678-01) is packaged within 2 larger trade packages. Cartons of 50 (1234-5678-50) and cartons of 80 (1234-5678-80).

Marketing ends for cartons of 50 on 9/30/2012. Marketing ends of carton of 80 on 12/31/2012.

- i. Based on the CMS letter, is this a valid example of when the earlier start date of 9/30/2012 would be used as the market end date?
 - Please confirm which date would be the market end date for the individual blister pack 1234-5678-01?
 - If a request for reimbursement for the single blister pack comes in with a Date of Service (DOS) of 12/15/2012 – will it be reimbursed?
- ii. If this example doesn't illustrate the when the earlier date would be used, then please provide another example.

4. Please review the CMS instructions in the May 14 letter (see excerpt below):

Please provide guidance on drug listing a new product that is planned to be launched on the 1st of the month:

- a. Do we need to send in drug listing by the 14th of the previous month? (We assume the answer is yes)
- b. What date do we put in for the launch date – the 14th of the previous month (so it gets posted to the NDC directory and CMS can see it) or the 1st of the month (the actual launch date)?

Timing Issues

CMS also realizes that timing may be an issue between the dates of PDE submissions and updates to the NSDE file used for PDE editing. Below are scenarios to help clarify these types of circumstances:

- An NDC listed on the NSDE file as of the 15th of each month will be used for PDE editing starting the 1st of the following month.
 - A new drug product (NDC) enters the market on August 19, 2012.
 - The NDC first appears on the November 15, 2012, NSDE file.
 - CMS editing file will implement the NDC on December 1, 2012.
 - CMS will reject PDEs for this NDC up to December 1, 2012.
 - PDEs for this NDC, regardless of date of service, should be resubmitted on or after December 1, 2012.
- The Marketing Category listed on the NSDE file as of the 15th of each month will be used for PDE editing starting the 1st of the following month.
 - NDC is listed on the August 15, 2012, NSDE file with an ANDA.
 - CMS editing file will implement an ANDA on September 1, 2012.
 - NDC changes its Marketing Category to an NDA on the September 15, 2012, NSDE file.
 - CMS editing file will implement an NDA on October 1, 2012.

Other Business:

5. Howard: There is a validation rule that requires the market start date to be after the day you submit your SPL for drug listing. One of Howard's clients received a validation error. Has anyone else had this problem?
 - a. When you try to drug list on the same day of approval, you also have to send an email to the SPL team alerting them that you got approval on that day.
 - b. Relates to natural time delay of communications within the FDA
6. Comments about a the process going forward:
 - a. Proposal for the future: We've come a long way to have validation rules published and explained to us in advance of implementation. It would be nice if FDA managed the rollout of future changes to the implementation of validation rules such that they occurred on specific dates/times of the year – instead of rolling them out sporadically – so that sponsors could plan to review their SPL files to make sure that everything is compliant.

- b. Concept of validation rules driving implementation is advantageous from a computer perspective. When the rules relate to regulations/guidances, there needs to be a roll-out and comment period.
- 7. Ruth: Issue with UNII and the pragmatic validator. UNII is correct per the searchable UNII site. However, they got an error from pragmatic validator --providone and hypromelloses. Lonnie said that is a problem with the pragmatic validator. They submitted it to drug listing even though they got an error, and the file passed FDA validation.
 - a. There is a problem with manual loads of data
 - b. Sometimes it goes right through at FDA
 - c. Sometimes it doesn't and you need to submit to work through
- 8. Perrigo: Duplicate NDC numbers.

Situation: Prior to 2009, they had listed something in paper format as the manufacturer for a PLD. Before they could drug list the product electronically, one of the PLD's other manufacturers drug listed another product electronically with their NDC that was listed only in paper.

 - a. Who owns the NDC code – the paper listing or the new electronic listing.
 - b. Has anyone else had this same situation come up? Yes GSK has had this situation come up and they worked it out through DRLS. They were able to contact the other manufacturer and work it out.
 - c. Advise: Send them an email with the situation and ask to set up a telephone discussion. Do this as soon as you know, because it is easier for the new lister to change theirs if they haven't already printed their labeling.
- 9. CBER requirement for different NDC codes on different levels of packaging. Outer carton and inner product have same NDC number-done this for 4 years – now this is not passing validation.
 - a. This is a CBER only interpretation and has been discussed at several SPL meetings. CBER is taking a strict interpretation of the bar code rule.
 - b. If you talk to Vada, he may give you time to change over and give you a manual override. GSK left the inner package NDC off of the SPL.